Q1: What are the BAA amendments? (11/17/10)

There have been three amendments to the BAA since its original posting. Please use the most recent version.

Amendment 1 (10/29/10): Typo corrected on page 33 which had an incorrect proposal due date.

Amendment 2 (11/9/10): Revised proposal due date. Was 12/9/10, now is 12/17/10.

Amendment 3 (11/10/10): States total program funding for the entire program is no more than approximately \$18M.

Q2: How important is the Cost Proposal? (11/3/10)

The cost proposal is <u>very</u> important. Please do not submit a poorly constructed cost proposal. A well prepared cost proposal (as described in Section 4-B-6 of BAA 11-08, "Volume II, Cost Proposal") will: (a) follow the checklist provided in Attachment 1 Cost-Proposal Checklist, (b) clearly break down costs by Technical Area, task (correlated with the Statement of Work), phase, fiscal year and (c) justify <u>all</u> expenses with price quotes for individual items associated with tasks, travel, staffing, etc. Please note, new equipment purchases will not be approved if the laboratory already owns equipment (or can share with another laboratory) that can function to fulfill the task. Please take the time to check for math errors and inconsistencies, they will reflect very poorly upon your proposal. We suggest that you read through your cost volume as if you were a non-technical government contract specialist performing their due diligence on behalf of the taxpayer, to identify the specific costs of each and every individual task for each and every technical area.

Q3: What, when, and where is the Proposers' Day? (12/1/10)

Please read the description in Section 8-F of BAA 11-08. The Proposers' Day was an opportunity to hear Dr. Judy discuss his vision for the program, directly ask him questions regarding BAA 11-08 that can only be answered publically, and meet other interested proposers. In the past, Proposers' Day has resulted in the formation of teams as well as a deeper appreciation for the goals of the program. The Proposers' Day meeting was held on November 8th, 2010 in Arlington, VA. We will post all of the presentations once every presentation has been cleared for public release.

Due to feedback from attendees, the proposal due date was extended by a week to 12/17/10.

Q4: Why is the language in the BAA so vague? (11/3/10)

This is intentional! DARPA does not want to restrict the creativity of the proposers. For example, Technical Area 1 is: "Demonstrate clinically viable reliable-tissue interfaces to peripheral nerves or muscles." If the BAA included the phrase "solutions might include technologies A, B, and C", then it is extremely likely that most proposals will promise to deliver only A, B, and C. This is not a desirable programmatic outcome, as DARPA would like to hear the creative thoughts of proposers using

technologies D, E, F. However, this vagueness does not suggest that proposals should be written in a manner that does not fully describe the technical approach and methods to achieve success.

Q5: Must I respond to all of the Technical Areas in the BAA? (11/3/10)

No. Only submit responses to the technical areas that strongly align with your strengths. It is perfectly acceptable to propose work that only addresses one of the technical areas.

However, if you feel your research interests are too narrow (but deep) to substantially contribute to the objectives of the BAA, you might consider teaming with other researchers at the BAA 11-08 Teaming Website: http://teaming.sysplan.com/BAA-11-08/ or during the Proposer's Day as noted above.

If your focus is extremely narrow, and you feel that BAA 11-08 may not be a good match for your research but it is still relevant to Dr. Judy's interests in *reliable* neural-interface technology, please contact him and Dr. Tracey Wheeler directly regarding a submission to the MTO Office-wide BAA http://www.darpa.mil/mto/solicitations/baa10-35/. Please send them both a PowerPoint presentation that clearly answers the four main Heilmeier questions: (1) indicate what do you want to do with no jargon, (2) thoroughly explain how it is done now, (3) demonstrate what is new in your approach, and (4) if you are successful, explain the expected DOD impact. You may also include a three-page white-paper describing your innovative ideas. Dr. Judy will be unable to correspond with you prior to December 2010, when the BAA 11-08 submissions are due. You should expect no more than a brief email receipt acknowledging that he has received your white paper.

Q6: Will teaming with other researchers be required? (11/3/10)

No, but with several caveats. Your proposal should focus on your core areas of strength. Do not add team members simply so you can respond to all Technical Areas of the BAA. If additional subcontractors, consultants, or other researchers will build a compelling response to the BAA, you should consider adding them to your team. Please read Section 3-C-1 of BAA 11-08, "Collaborative Efforts".

Note: DARPA reserves the right to fund only portions of your proposal. Please read Section 2 paragraph 2 of BAA 11-08, "Award Information".

Q7: How long will this program last? (11/3/10)

Please read Section 1 of BAA 11-08, "Funding Opportunity Description", in particular the subsection entitled "Guidelines for Program Phases and Milestones". The RPI BAA is expected to have a duration of 3 years. Proposers are expected to design their research plan such that very significant advances will be accomplished in the first year. The total period of performance should be broken down into distinct phases. The number and duration of each phase is at your discretion. Phases should not overlap in time and should end with the accomplishment of major objectives for each task. Should initial results be promising, Dr. Judy will have a strong case to continue funding your effort, especially given the current fiscally constrained environment.

Q8: What is entailed in a PI Meeting? (11/3/10)

Section 6-B-1 of BAA 11-08, "1. Meeting and Travel Requirements" describes PI Meetings. Briefly, PIs are expected to meet with the Program Manager and the other PIs awarded under this program. This will occur roughly twice a year in a closed meeting. It is expected that PIs will freely share their research results with each other and the Program Manager. The Program Manager would like to instill a "team spirit" among all of the performers in this program, such that the overall goals will be achieved.

Q9: How much money should I ask for? (11/3/10)

As much as it takes to achieve the objectives you describe in your proposal. If DARPA were to list a cap of \$X, then most proposals would request \$X-1. Your cost should be based primarily upon how much money is required to perform the research you feel is necessary to meet the objectives in the Technical Areas described in Section 1 of BAA 11-08. Please bear in mind, however, that in this case DARPA prefers to fund multiple independent efforts instead of one single large effort. Proposals must be fiscally conservative and will be scrutinized for unnecessary or inflated expenses. Take great care to demonstrate that the funding you request is the minimum amount needed to achieve the innovations described in the proposal.

If your proposal is selected to be awarded, then a government contract office will negotiate the terms of the grant or contract. During this negotiation phase, every aspect of your statement of work and cost proposal (as described in Section 4-B-6 of BAA 11-08, "Volume II, Cost Proposal") will be negotiated. Please ensure that you have followed all of the instructions in BAA 11-08, including the required checklist in Attachment 1. This will enable the government contract office to expedite negotiations.

Q10: Should I budget for collaboration with parties not included in the proposed team? (11/17/10)

No. Should your proposal be selected for funding, this would be negotiated as part of the contracting process. It will be easier to determine an accurate cost once everyone understands the scope and extent of such collaboration.

Q11: Could you provide more details regarding the funding set aside for this effort? (12/6/10)

We have set aside approximately \$18 M in funds for all 3 years of the effort in anticipation that there will be multiple efforts funded. Please read the first paragraph of Section II in BAA 11-08 for more information.

Q12: Page 32 of the BAA states, "Indirect Costs (See Note 2)..." Where is Note 2? (11/17/10)

Please disregard the Note 2 reference. The missing "Note 2" refers to an indirect cost cap for 6.1 funding. This does not apply to BAA 11-08 since funding is expected to be 6.2 Applied Research and should have been deleted from the BAA.

Q13: What is the timeline for this program? (11/3/10)

Please read page 3 of BAA 11-08. There is no Abstract phase of this solicitation. Full proposals (as defined in Section 4-B-4, "Full Proposal Format") are due on December 17, 2010. DARPA will select awards and notify the awardees as soon as possible. DARPA does not speculate or make any promises on this notification date, or the duration of the contracting process. We are hopeful that grants or contracts will be awarded as early as March/April 2011, but the process may extend into May/June 2011 or later depending on contracting as well as the performer's schedule.

Q14: What animal model is appropriate for this research? (11/3/10)

That is left for the proposer to determine. Please justify your choice based on cost effectiveness, number required (based on thorough power analyses), ethical considerations, and relevance to achieving the goals of the RPI BAA. For each task of each technical area, please clearly state the species, number of animals you propose, and the IACUC procedures to be followed. If you plan to perform human testing, clearly state so, describe the HSR procedures to be followed, and the number of participants.

Q15: Are non-amputee models acceptable for RPI? (11/3/10)

Yes, but with great reservation. Proposers must be able to clearly identify the differences between amputee and non-amputee experimental design and interpretation of experimental results. This explanation must include a compelling argument that clearly and fully demonstrates the transferability of the proposed innovation to amputees. Emphasis must be placed on the vast differences in nerve function between amputee and non-amputee subjects, how these differences will be accounted for, and how demonstrations of success would be equivalent in an amputee model.

Q16: Will you accept proposals on cortical or spinal cord interfaces? (11/17/10)

No. This solicitation is focused entirely on extracting motor-control information and providing sensory input to the peripheral system. DARPA may consider starting a separate program to construct, integrate, and test new Central Nervous System (CNS) interfaces. For the purposes of this BAA, the PNS includes the brachial plexus and all other peripheral spinal nerves up to and including the dorsal root (sensory), ventral root (motor), and the dorsal root ganglion. All parts of the CNS and all cranial nerves, with the exception of cranial nerve XI (accessory), are excluded from this solicitation. Specifically excluded is research that lacks scalability and a credible transition pathway to human use.

That said, proposed work which uses CNS information to validate information from a peripheral interface is within the scope of the BAA.

Q17: Can we propose an interface that is dually dependent on the CNS and PNS? (11/17/10)

This situation was not anticipated when the RE-NET effort was designed. If your interface is dually dependent on both the CNS and PNS, then you could respond to either the RPI or RCI BAAs. However, in

order to respond to the RPI BAA the majority of the motor-control information should be extracted from the periphery.

Q18: Can we measure PNS functionality by taking CNS measurements? (11/17/10)

Yes. If your interface is resides in the periphery, but you measure CNS activity to confirm functionality, then it is responsive to the BAA. If CNS information is used to decode signals, versus confirm them, then you should not respond to this BAA and wait for the RCI effort which is targeted for release early next year.

Q19: Will you accept proposals on research independent of the interface location? (11/17/10)

Although some technological developments may be suitable for both RPI and potential future DARPA programs focused on CNS approaches, any response to the RPI BAA must be informed by the practical constraints of interfacing with the periphery.

Q20: What does channel mean? (11/17/10)

The word channel indicates a source of distinct signal information. Whereas input channels independently capture biological data, output channels are independent motor-control representations of one or more input channels.

Q21: What does "a continuous transfer function and a dynamic range of 60 dB for each independent output channel" mean? (11/17/10)

Biological motor-control signals captured by a proposed peripheral interface may vary tremendously in terms of amplitude, frequency, and noise level. The proposed decoder must take these captured signals and describe them as electronic motor-control output signals with the range and resolution needed to be used by advanced prostheses. The decoder effectively performs a transfer function that maps captured input to motor-control output in a reasonably uniform or continuous fashion.

Digitally, the decoder output can be thought of in terms of the effective number of bits (ENOB) of motor control. However, this can convey an assumed sense of linearity which may be inappropriate for some approaches, given the inherent nonlinear properties of the biological signals. In analog terms, the decoder output must have a quantifiable dynamic range (i.e., between the maximum and minimum amplitudes of the motor-control signal) described in a logarithmic decibel scale. Thus, proposed decoders must demonstrate an ENOB of ~10 (i.e., a dynamic range of ~60 dB) per independent motor-control output channel after taking into account the uncertainty in the decoded signal.

Q22: What does 99% functionality mean? (11/17/10)

It means that the false-positive and false-negative decoding error rates must be below 1% during all functional assessments throughout the proposed effort. In order to demonstrate this 80% of the time, an extremely large study size may be required. If you determine that the required study size exceeds a practical timeframe and budget, provide a through explanation of your proposed study design. Your

proposed design will be considered and thoroughly reviewed as it relates to a realistic sample size for the duration of the effort.

Q23: Is it possible to "Develop scalable and platform-appropriate algorithms that can reliably interpret the peripheral motor-control signals detected by physical interfaces" for TA3 in-silico? (11/3/10)

Yes. Synthetic data analyses (if justified as relevant for achieving the overall goals of the BAA) can be used to develop, test, and demonstrate novel reliable decoding algorithms without the use of animal testing.

Q24: Is it necessary to use an advanced prosthesis for RPI? (11/3/10)

No. Although advanced prostheses may be used, they are not required for this BAA. Demonstrations could include, but are not limited to, virtual reality, predictive trajectory calculations, or control of other behavioral-assessment experimental devices.

Q25: Can you provide more explanation about the "block diagrams" required in RPI proposals? (11/3/10)

Very briefly, an RPI block diagram should visually convey the route that peripheral information takes as it is measured, processed, and communicated in a proposed implementation. At each step of this path, the block diagram should clearly describe the block's functional capabilities, physical properties, and a description of the information received and sent between adjacent blocks. Additionally, each block should indicate the corresponding task number, required resource allocation, and expected cost.

Respondents that do not propose to deliver a complete system addressing all Technical Areas are still required to include a complete high-level block diagram and narrative text in order to be considered responsive. Portions of the block diagram that are not deliverables of the proposal must be clearly identified. Inclusion of these "non-deliverable" blocks will provide a full picture of how the proposed technology would be incorporated into a complete system.

In addition:

- Blocks involving test subjects must justify the choice of test subjects.
- Proposals not responding to TA1 must clearly describe the source of the peripheral motor-signal information used to evaluate the performance of the proposed technology.
- Although the use of an advanced neural prosthesis is not required for RPI, the resulting technology should be able to communicate with it directly or with minimal additional effort.
- Proposed tissue-interface technologies that must be periodically donned/doffed, connected, adjusted, cleaned, aligned, recharged, or maintained, must address not only performance and functional reliability but also ease of use.

Proposers should note that blocks may be evaluated and selected individually in order to best achieve the overall goals of this solicitation.

Q26: Regarding packaging, does the interface need to be hermetically sealed or is there a specific type of packaging required? (11/17/10)

There is no specific type of packaging required. The packaging must enable experiments that achieve the reliability measures required. If this can be demonstrated without a hermetic seal then it would be acceptable.

Q27: During proposer's day we were told the FDA would do independent testing, how much should we budget for this testing? (12/6/10)

None. There are funds in place for the FDA to perform all necessary tests. If your research involves development of novel materials, then samples may need to be sent to the FDA for use in their laboratory. The remaining costs for animals and testing will be covered by the FDA.

Note:

This is the third posted version of the RPI FAQ. New or modified entries are indicated with a posting date of (12/6/10). Original entries have a posting date of (11/3/10).